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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,046	04/30/2001	Peter Hevezi	A-69199-1/DJB/JJD	5223

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EXAMINER

DAVIS, MINH TAM B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/847,046

Applicant(s)

HEVEZI ET AL.

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 September 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Election/Restriction***

I. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-2 are drawn to a method for screening drug candidates that effect the expression of an expression profile gene encoding PAA3, classified in class 435, subclass 6.

Group II. Claim 3 is drawn to a method for screening an agent that binds PAA3, classified in class 435, subclass 7.1.

Group III. Claim 4 is drawn to a method for screening an agent that modulates the activity of PAA3, classified in class 435, subclass 7.1

Groups IV. Claims 5-6 are drawn to a method for evaluating the effect of a prostate or breast cancer drug candidate, classified in class 435, subclass 6.

Group V. Claim 7 is are drawn to a method for diagnosis of prostate cancer, comprising determining the expression of a gene encoding PAA3, classified in class 435, subclass 6.

Group VI. Claim 7 is are drawn to a method for diagnosis of breast cancer, comprising determining the expression of a gene encoding PAA3, classified in class 435, subclass 6.

Group VII. Claims 8-13, drawn to an antibody specific for PAA3, classified in class 530, subclass 387.1.

Group VIII. Claims 14-15 is drawn to a method for screening an agent capable of interfering with the binding of PAA3 or a fragment thereof, and an antibody which binds to PAA3 or a fragment thereof, classified in class 435, subclass 4 and 7.1.

Group IX. Claims 16-18 are drawn to a method for inhibiting the activity or neutralizing the effect of PAA3, classified in class 424, subclass 130.1.

Group X. Claims 19-26 are drawn to 1) a method for treating prostate cancer, comprising administering an inhibitor of PAA3, or an antibody which is an inhibitor of PAA3, and 2) a method for localizing a therapeutic moiety to prostate or breast cancer tissue, or treating prostate or breast cancer, comprising exposing said tissue to or administering an antibody to PAA3 or fragment thereof conjugated to a therapeutic moiety, classified in class 424, subclass 130.1.

Group XI. Claims 19-26 are drawn to 1) a method for treating breast cancer, comprising administering an inhibitor of PAA3, or an antibody which is an inhibitor of PAA3, and 2) a method for localizing a therapeutic moiety to prostate or breast cancer tissue, or treating prostate or breast cancer, comprising exposing said tissue to or administering an antibody to PAA3 or fragment thereof conjugated to a therapeutic moiety, classified in class 424, subclass 130.1.

Group XII. Claim 27 is drawn to a method for inhibiting prostate cancer in a cell, comprising administering antisense molecules to a nucleic acid of figure 1, classified in class 514, subclass 4.

Group XIII. Claim 27 is drawn to a method for inhibiting breast cancer in a cell, comprising administering antisense molecules to a nucleic acid of figure 1, classified in class 514, subclass 4.

Group XIV. Claim 28 is drawn to a biochip comprising one or more nucleic acid segments encoding PAA3, classified in class 536, subclass 23.1.

Group XV. Claim 29 is drawn to a method for eliciting an immune response in an individual, comprising administering PAA3, classified in class 514, subclass 2.

Group XVI. Claim 30 is drawn to a method for eliciting an immune response in an individual, comprising administering a sequence of a nucleic acid encoding PAA3, classified in class 514, subclass 44.

Group XVII. Claim 31 is are drawn to a method for prognosis of prostate cancer, comprising determining the level of the protein PAA3, classified in class 435, subclass 7.1.

Group XVIII. Claim 31 is are drawn to a method for prognosis of breast cancer, comprising determining the level of the protein PAA3, classified in class 435, subclass 7.1.

Group XIX. Claims 32-35, drawn to the polypeptide of SEQ ID NO:2 or a polypeptide encoded by nucleotides 375 to 2795 of SEQ ID NO:1, classified in class 530, subclass 350.

Group XX. Claims 36-38, drawn to the nucleic acid sequence of SEQ ID NO:1, or a polynucleotide encoding the polypeptide of SEQ ID NO:2 or a polynucleotide comprising nucleotides 375 to 2795 of SEQ ID NO:1, classified in class 536, subclass 23.1.

In addition, Group XI is further subjected to the following species election requirement:

Cytotoxic agent or radioisotope.

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II. The inventions are distinct, each from the other because of the following reasons:

Inventions recited in groups (VII, XIV, XIX, XX) and (I-VI, VIII-XIII, XV-XVIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h)). In this instant case, a polypeptide could be used for several purposes, e.g. for biochemical assay, for making antibodies, and for making an affinity column to purify its antibodies; a DNA sequence could be used for the detection of similar DNA or RNA sequences, for making an expression vector, and for producing its encoded protein; and an antibody could be used for immunoassay, for purification of its antigen, and for detection of diseases.

The products of the inventions recited in groups VII, XIV, XIX, XX are patentably distinct, because they are drawn to entirely different biochemicals, having different structures, biological properties and activities.

The methods of the inventions recited in groups I-VI, VIII-XIII, XV-XVIII are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species cytotoxic agent and radioisotope are distinct because they are functionally and structurally distinct.

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Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that if a group having species election requirement is elected, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if

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one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

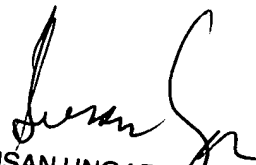
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

August 24, 2002

  
SUSAN UNGAR, R.M.D.  
PRIMARY EXAMINER